



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

5

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/652,001

08/31/2000

Alan Krasberg

P56156

2933

7590

06/03/2004

Robert E Bushnell
1522 K Street
Suite 300
Washington, DC 20005-1202

EXAMINER

LEWIS, AARON J

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 06/03/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/652,001

Applicant(s)

KRASBERG, ALAN

Examiner

AARON J. LEWIS

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/25/2004 (AMENDMENT).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13, 15-22, 24-29, 31-33, 35-50 and 53-71 is/are pending in the application.
- 4a) Of the above claim(s) 16, 18-22, 24-28, 31, 33, 35-50, 53-57, 64 and 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13, 15, 17, 29, 32, 58-63, 65-68, 70 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 8,9,13,15,71 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrett et al. (GB 2,331,707).

As to claim 8, Garrett et al. disclose a method of providing protection from reactive oxygen species, the method comprising the steps of: preparing a breathable composition comprising oxygen (6) intentionally supplemented with a fuel gas (4); providing said breathable composition to an animal (2) on land while the animal is surrounded by a gaseous environment; and within said animal, scavenging said reactive oxygen species with said fuel gas. In Garrett et al. the fuel gas is hydrogen (4) and the delivery of the mixture of oxygen and hydrogen to a patient (2) would inherently provide the recited intended use of protection from reactive oxygen species by chemically combining with the reactive oxygen species within a patient's body thereby scavenging said reactive oxygen species.

As to claim 9, the animal in Garrett et al. is disclosed as a human being (2).

As to claims 13 and 15, the fuel gas in Garrett et al. is expressly disclosed as being hydrogen, the disclosed breathable mixture of oxygen and hydrogen also disclosed as being an explosive composition (page 1, lines 15-21).

As to claim 71, Garrett et al. disclose a method of providing protection from reactive oxygen species, the method comprising the steps of: preparing a breathable composition consisting essentially of oxygen (6) intentionally supplemented with hydrogen gas (4); providing said breathable composition to an animal (2) on land; and within said animal, scavenging said reactive oxygen species with said hydrogen gas. In Garrett et al. the fuel gas is hydrogen (4) and the delivery of the mixture of oxygen and hydrogen to a patient (2) would inherently provide the recited intended use of protection from reactive oxygen species by chemically combining with the reactive oxygen species within a patient's body thereby scavenging said reactive oxygen species.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 10-12,17,29,58-60,62,63,65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al. (GB 2,331,707).

As to claims 10-12,58-60, the particular duration of administration of the oxygen/fuel gas mixture to a patient in Garrett et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular time period. That is, it would have been obvious to employ a time period of administration that is suitable to the particular medical needs of a given patient. The time duration of

administration would vary in dependence upon whether the patient was a child or adult and upon whether an adult patient was elderly or young.

As to claim 17, the particular pressure of the breathable composition in Garrett et al. is supplied to a patient is not expressly disclosed; however, one of ordinary skill would have realized that given a spontaneously breathing patient (2) on land, a pressure of at least atmospheric pressure would be necessary to accomplish delivery of a breathable gas to the lungs of a spontaneously breathing patient.

As to claims 29 and 63, Garrett et al. (page 2, lines 20-21) discloses the delivery and preparation of the breathable gas composition by providing the constituents (oxygen and hydrogen) to a mixing chamber within mask (8). While Garrett et al. disclose the use of oxygen, it would have been obvious to modify the oxygen source to substitute ambient air to a patient that did not have a medical need for pure oxygen inasmuch as ambient air contains at least 21% oxygen.

As to claim 62, while Garrett et al. disclose the delivery of hydrogen gas to patients, it is submitted that it would have been obvious to substitute any one of a plurality of well known fuel gases for hydrogen including acetylene as substitution of one fuel gas for another with no new or unobvious results accruing. That is, inasmuch as both hydrogen and acetylene are fuel gases, the administration of acetylene or hydrogen would have been equally effective in the treatment of patients.

As to claim 65, Garrett et al. disclose a method of providing protection from reactive oxygen species, the method comprising the steps of: preparing a breathable composition comprising oxygen (6) intentionally supplemented with a fuel gas (4);

Art Unit: 3743

providing an animal (2) on land while surrounded by a gaseous environment with said breathable composition; and within said animal, scavenging said reactive oxygen species with said fuel gas. In Garrett et al. the fuel gas is hydrogen (4) and the delivery of the mixture of oxygen and hydrogen to a patient (2) would inherently provide the recited intended use of protection from reactive oxygen species by chemically combining with the reactive oxygen species within a patient's body thereby scavenging said reactive oxygen species. With respect to the use of acetylene as a fuel gas, while Garrett et al. disclose the delivery of hydrogen gas to patients, it is submitted that it would have been obvious to substitute any one of a plurality of well known fuel gases for hydrogen including acetylene as substitution of one fuel gas for another with no new or unobvious results accruing. That is, inasmuch as both hydrogen and acetylene are fuel gases, the administration of acetylene or hydrogen would have been equally effective in the treatment of patients.

As to claim 66, Garrett et al. (page 2, lines 20-21) discloses the delivery and preparation of the breathable gas composition by providing the constituents (oxygen and hydrogen) to a mixing chamber within mask (8). While Garrett et al. disclose the use of oxygen, it would have been obvious to modify the oxygen source to substitute ambient air to a patient that did not have a medical need for pure oxygen inasmuch as ambient air contains at least 21% oxygen.

As to claims 67 and 68, the breathable gas composition of Garrett et al. is intentionally supplemented with the fuel gas hydrogen (4).

Art Unit: 3743

5. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al. as applied to claims 10-12, 17, 29, 58-60, 62, 63, 65-68 above, and further in view of Monnier ('563).

The difference between Garrett et al. and claim 32 is regulating the rate of supply of said fuel gas to the respiratory tract.

Monnier teaches regulating the rate of supply of oxygen and medicament gas (11,21) to the respiratory tract of patients for the purpose of accurately metering the amounts of oxygen and medicament gas thereby providing a safe and effective mixture to patients.

It would have been obvious to modify Garrett et al. to regulate the rate of supply of said fuel gas to a patient's respiratory tract because it would have enabled accurate metering of the amounts of oxygen and medicament gas thereby providing a safe and effective mixture to patients as taught by Monnier.

6. Claims 61 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al. in view of Lake ('180).

The difference between Garrett et al. and claim 61 is the step of providing the breathable composition under a hyperbaric condition.

Lake teaches the step of providing a breathable gas composition to patients under both hyperbaric and hypobaric conditions for the purpose of forcing a greater quantities of breathable gas into contact with diseased cells within a patient's body (page 1, lines 23-36).

It would have been obvious to modify the method of breathable gas delivery in Garrett et al. to include the step of providing the breathable composition under hyperbaric conditions because it would have forced greater quantities of breathable gas into contact with diseased cells within a patient's body as taught by Lake.

As to claim 70, Lake also teaches providing a breathable gas composition to patients under hypobaric conditions.

Response to Arguments

7. Applicant's arguments with respect to claims 8-13,15,17,29,32,58-63,65-68,70,71 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

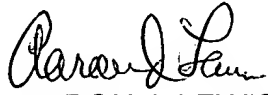
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant fuel gas and oxygen mixtures being provided as breathable gas mixtures and relevant gas flow control devices for metering breathable gas flow to patients.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
May 27, 2004